



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/121,849	07/24/98	GARFIELD	R SCH1237DI

EXAMINER	
LILLING, H	

ART UNIT	PAPER NUMBER
1651	4

DATE MAILED: 07/08/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on July 24, 1998

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ONE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-33 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-33 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

Serial 09/121849

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

1. Receipt is acknowledged of the preliminary amendment filed July 24, 1998.

2. Claims 1-33 are present in the instant application.

5

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

10 I. Claims 1-13, 22-27 and 32-33 drawn to a method of treating preeclampsia, classified in Class 514, subclass 310.

II. Claims 14-21 and 28-31 drawn to a pharmaceutical composition, classified in Class 514, subclass 310+.

15 4. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the

20

instant case, the product compositions can be used in a materially different process of using that product, e.g. control high blood pressure.

5 5. Because these inventions are distinct for the reasons
 given above and have acquired a separate status in the art as shown
 by their different classification, have acquired a separate status
 in the art because of their recognized divergent subject matter and
 the search required for one invention is not required for the other
10 invention, thusly the restriction for examination purposes as
 indicated is proper.

 6. This application contains claims directed to the
15 following patentably distinct species of the claimed invention:

- I. Whereby the composition and processes contain
 - a. nitric oxide synthase substrate
 - b. nitric oxide donor

20

and

whereby the nitric oxide donor is
selected from the group consisting of:

bi. sodium nitroprusside

bii. nitroglycerin

bihi.glyceryltrinitrate

biv. SIN-1

bv. isosorbidmononitrate or
isosorbiddninitrate

5

10

c. both a and b.

II. Whereby compositions and processes contains

i. cyclooxygenase inhibitor

ii. a compound containing PGI₂-agonistic and
TXA₂-inhibitiing properties,

iii. compound possessing TXA₂-antagonistic
and PGI₂-memetic activities
and whereby the memetic is

iiia. iloprost

iiib. cicaprost

iv. TXA₂ antagonist

v. a thromboxane (TXA₂) inhibitor

15

20

vi. more than one of the above-please
specify

vii. composition or processes absent i-vi.

5 Applicant is required under 35 U.S.C. § 121 to elect a single
disclosed species for prosecution on the merits to which the claims
shall be restricted if no generic claim is finally held to be
allowable. Currently, claims 1 and 14 are generic.

10 Applicant is advised that a response to this requirement must
include an identification of the species that is elected consonant
with this requirement, and a listing of all claims readable
thereon, including any claims subsequently added. An argument that
a claim is allowable or that all claims are generic is considered
nonresponsive unless accompanied by an election.

15 Upon the allowance of a generic claim, applicant will be
entitled to consideration of claims to additional species which are
written in dependent form or otherwise include all the limitations
of an allowed generic claim as provided by 37 C.F.R. § 1.141. If
20 claims are added after the election, applicant must indicate which
are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are
not patentably distinct, applicant should submit evidence or
identify such evidence now of record showing the species to be
25 obvious variants or clearly admit on the record that this is the
case. In either instance, if the examiner finds one of the
inventions unpatentable over the prior art, the evidence or
admission may be used in a rejection under 35 U.S.C. § 103 of the
other invention.

30 7. Applicant is advised that the response to this
requirement to be complete must include an election of the
invention to be examined even though the requirement be traversed.

It is noted that Applicant has correctly stated the restriction requirement between Invention I and II. In addition Applicant has also complied with the election of nitric oxide donor for I and nitroglycerin.

5 The requirement for election of species must be as noted in above paragraph 6, Pt II for the various Species indicated in II.

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor
10 errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner
15 Lilling whose telephone number is (703) 308-2034. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

20 H.J.Lilling: HJL
 (703) 308-2034
 Art Unit 1651
 July 06, 1999


HERBERT J. LILLING
PATENT EXAMINER
GROUP 1600- ART UNIT 1651